

1 AN ACT relating to controlled substance monitoring.

2 ***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

3 ➔Section 1. KRS 218A.202 is amended to read as follows:

4 (1) The Cabinet for Health and Family Services shall establish ***and maintain*** an  
5 electronic system for monitoring Schedules II, III, IV, and V controlled substances ~~that are dispensed within the Commonwealth by a practitioner or pharmacist or~~  
6 ~~dispensed to an address within the Commonwealth by a pharmacy that has obtained~~  
7 ~~a license, permit, or other authorization to operate from the Kentucky Board of~~  
8 ~~Pharmacy~~. The cabinet may contract for the design, upgrade, or operation of this  
9 system if the contract preserves all of the rights, privileges, and protections  
10 guaranteed to Kentucky citizens under this chapter and the contract requires that all  
11 other aspects of the system be operated in conformity with the requirements of this  
12 or any other applicable state or federal law.

14 (2) A practitioner or a pharmacist authorized to prescribe, ***administer***, or dispense  
15 controlled substances to humans shall register with the cabinet to use the system  
16 provided for in this section and shall maintain such registration continuously during  
17 the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or  
18 tax specifically dedicated to the operation of the system.

19 (3) Every ***practitioner or pharmacist***~~dispenser within the Commonwealth~~ who is  
20 licensed, permitted, or otherwise authorized to ***administer***~~prescribe~~ or dispense a  
21 controlled substance to a person ***in Kentucky, or for delivery to a person at an***  
22 ***address*** in Kentucky shall report to the Cabinet for Health and Family Services the  
23 data required by this section, except that reporting shall not be required for:

24 (a) A drug administered directly to a patient ***receiving inpatient care*** in a  
25 hospital, a resident of a health care facility licensed under KRS Chapter 216B,  
26 a resident of a child-caring facility as defined by KRS 199.011, or an  
27 individual in a jail, correctional facility, or juvenile detention facility; ***or***

1 (b) ~~[A drug, other than any Schedule II controlled substance or a Schedule III~~  
 2 ~~controlled substance containing hydrocodone, dispensed by a practitioner at a~~  
 3 ~~facility licensed by the cabinet, provided that the quantity dispensed is limited~~  
 4 ~~to an amount adequate to treat the patient for a maximum of forty eight (48)~~  
 5 ~~hours; or~~

6 (e) ~~]~~A drug administered or dispensed to a research subject enrolled in a research  
 7 protocol approved by an institutional review board that has an active  
 8 federalwide assurance number from the United States Department of Health  
 9 and Human Services, Office for Human Research Protections, where the  
 10 research involves single, double, or triple blind drug administration or is  
 11 additionally covered by a certificate of confidentiality from the National  
 12 Institutes of Health.

13 (4) **In addition to the data required by subsection (5) of this section, a Kentucky-**  
 14 **licensed acute care hospital or critical access hospital shall report to the cabinet**  
 15 **all positive toxicology screens that were performed by the hospital's emergency**  
 16 **department prior to the patient's admission to the hospital to evaluate the**  
 17 **patient's suspected drug overdose.**

18 **(5)** Data for each controlled substance that is **administered or** dispensed shall include  
 19 but not be limited to the following:

- 20 (a) Patient identifier;
- 21 (b) National drug code of the drug dispensed;
- 22 (c) Date of dispensing;
- 23 (d) Quantity dispensed;
- 24 (e) Prescriber; and
- 25 (f) Dispenser.

26 **(6)**~~(5)~~ The data shall be provided in the electronic format specified by the Cabinet  
 27 for Health and Family Services unless a waiver has been granted by the cabinet to

1 an individual dispenser. The cabinet shall establish acceptable error tolerance rates  
2 for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete  
3 or inaccurate data shall be corrected upon notification by the cabinet if the dispenser  
4 exceeds these error tolerance rates.

5 ~~(7)~~~~(6)~~ The Cabinet for Health and Family Services shall only disclose data to  
6 persons and entities authorized to receive that data under this section. Disclosure to  
7 any other person or entity, including disclosure in the context of a civil action where  
8 the disclosure is sought either for the purpose of discovery or for evidence, is  
9 prohibited unless specifically authorized by this section. The Cabinet for Health and  
10 Family Services shall be authorized to provide data to:

- 11 (a) A designated representative of a board responsible for the licensure,  
12 regulation, or discipline of practitioners, pharmacists, or other person who is  
13 authorized to prescribe, administer, or dispense controlled substances and who  
14 is involved in a bona fide specific investigation involving a designated person;
- 15 (b) Employees of the Office of the Inspector General of the Cabinet for Health  
16 and Family Services who have successfully completed training for the  
17 electronic system and who have been approved to use the system, *federal*  
18 *prosecutors*, Kentucky Commonwealth's attorneys and assistant  
19 Commonwealth's attorneys, county attorneys and assistant county attorneys, a  
20 peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-  
21 time peace officer of another state, or a federal *agent*~~peace officer~~ whose  
22 duty is to enforce the laws of this Commonwealth, of another state, or of the  
23 United States relating to drugs and who is engaged in a bona fide specific  
24 investigation involving a designated person;
- 25 (c) A state-operated Medicaid program in conformity with subsection ~~(8)~~~~(7)~~ of  
26 this section;
- 27 (d) A properly convened grand jury pursuant to a subpoena properly issued for the

1 records;

2 (e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's  
3 practice acting under the specific direction of the practitioner or pharmacist,  
4 who ~~requests information and~~ certifies that the requested information is for  
5 the purpose of:

6 1. Providing medical or pharmaceutical treatment to a bona fide current or  
7 prospective patient; ~~or~~

8 2. **Reviewing data on controlled substances that have been administered**  
9 **or dispensed to the birth mother of an infant who is currently being**  
10 **treated by the practitioner for neonatal abstinence syndrome; or has**  
11 **symptoms that suggest prenatal drug exposure; or**

12 **3.** Reviewing and assessing the individual prescribing or dispensing  
13 patterns of the practitioner or pharmacist or to determine the accuracy  
14 and completeness of information contained in the monitoring system;

15 (f) The chief medical officer of a hospital or long-term-care facility, an employee  
16 of the hospital or long-term-care facility as designated by the chief medical  
17 officer and who is working under his or her specific direction, or a physician  
18 designee if the hospital or facility has no chief medical officer, if the officer,  
19 employee, or designee certifies that the requested information is for the  
20 purpose of providing medical or pharmaceutical treatment to a bona fide  
21 current or prospective patient or resident in the hospital or facility;

22 (g) In addition to the purposes authorized under paragraph (a) of this subsection,  
23 the Kentucky Board of Medical Licensure, for any physician who is:

24 1. Associated in a partnership or other business entity with a physician who  
25 is already under investigation by the Board of Medical Licensure for  
26 improper prescribing or dispensing practices;

27 2. In a designated geographic area for which a trend report indicates a

- 1                   substantial likelihood that inappropriate prescribing or dispensing may  
2                   be occurring; or
- 3           3.   In a designated geographic area for which a report on another physician  
4                   in that area indicates a substantial likelihood that inappropriate  
5                   prescribing or dispensing may be occurring in that area;
- 6           (h)   In addition to the purposes authorized under paragraph (a) of this subsection,  
7                   the Kentucky Board of Nursing, for any advanced practice registered nurse  
8                   who is:
- 9                   1.   Associated in a partnership or other business entity with a physician who  
10                   is already under investigation by the Kentucky Board of Medical  
11                   Licensure for improper prescribing or dispensing practices;
- 12                   2.   Associated in a partnership or other business entity with an advanced  
13                   practice registered nurse who is already under investigation by the Board  
14                   of Nursing for improper prescribing practices;
- 15                   3.   In a designated geographic area for which a trend report indicates a  
16                   substantial likelihood that inappropriate prescribing or dispensing may  
17                   be occurring; or
- 18                   4.   In a designated geographic area for which a report on a physician or  
19                   another advanced practice registered nurse in that area indicates a  
20                   substantial likelihood that inappropriate prescribing or dispensing may  
21                   be occurring in that area;
- 22           (i)   A judge or a probation or parole officer administering a diversion or probation  
23                   program of a criminal defendant arising out of a violation of this chapter or of  
24                   a criminal defendant who is documented by the court as a substance abuser  
25                   who is eligible to participate in a court-ordered drug diversion or probation  
26                   program; or
- 27           (j)   A medical examiner engaged in a death investigation pursuant to KRS 72.026.

1 ~~(8)~~~~(7)~~ The Department for Medicaid Services shall use any data or reports from the  
2 system for the purpose of identifying Medicaid providers or recipients whose  
3 prescribing, dispensing, or usage of controlled substances may be:

4 (a) Appropriately managed by a single outpatient pharmacy or primary care  
5 physician; or

6 (b) Indicative of improper, inappropriate, or illegal prescribing or dispensing  
7 practices by a practitioner or drug seeking by a Medicaid recipient.

8 ~~(9)~~~~(8)~~ A person who receives data or any report of the system from the cabinet shall  
9 not provide it to any other person or entity except as provided in this section, in  
10 another statute, or by order of a court of competent jurisdiction and only to a person  
11 or entity authorized to receive the data or the report under this section, except that:

12 (a) A person specified in subsection ~~(7)~~~~(6)~~(b) of this section who is authorized  
13 to receive data or a report may share that information with any other persons  
14 specified in subsection ~~(7)~~~~(6)~~(b) of this section authorized to receive data or  
15 a report if the persons specified in subsection ~~(7)~~~~(6)~~(b) of this section are  
16 working on a bona fide specific investigation involving a designated person.  
17 Both the person providing and the person receiving the data or report under  
18 this paragraph shall document in writing each person to whom the data or  
19 report has been given or received and the day, month, and year that the data or  
20 report has been given or received. This document shall be maintained in a file  
21 by each agency engaged in the investigation;

22 (b) A representative of the Department for Medicaid Services may share data or  
23 reports regarding overutilization by Medicaid recipients with a board  
24 designated in subsection ~~(7)~~~~(6)~~(a) of this section, or with a law enforcement  
25 officer designated in subsection ~~(7)~~~~(6)~~(b) of this section;

26 (c) The Department for Medicaid Services may submit the data as evidence in an  
27 administrative hearing held in accordance with KRS Chapter 13B;

- 1 (d) If a state licensing board as defined in KRS 218A.205 initiates formal  
 2 disciplinary proceedings against a licensee, and data obtained by the board is  
 3 relevant to the charges, the board may provide the data to the licensee and his  
 4 or her counsel, as part of the notice process required by KRS 13B.050, and  
 5 admit the data as evidence in an administrative hearing conducted pursuant to  
 6 KRS Chapter 13B, with the board and licensee taking all necessary steps to  
 7 prevent further disclosure of the data; and
- 8 (e) A practitioner, pharmacist, or employee who obtains data under subsection  
 9 ~~(7)(6)~~(e) of this section may share the report with the patient or person  
 10 authorized to act on the patient's behalf. **Any practitioner, pharmacist, or**  
 11 **employee who obtains data under subsection (7)(e) of this section may** ~~and~~  
 12 place the report in the patient's medical record, **in which case the** ~~with that~~  
 13 individual report **shall** then **be** ~~being~~ deemed a medical record subject to  
 14 disclosure on the same terms and conditions as an ordinary medical record in  
 15 lieu of the disclosure restrictions otherwise imposed by this section.
- 16 ~~(10)(9)~~ The Cabinet for Health and Family Services, all peace officers specified in  
 17 subsection ~~(7)(6)~~(b) of this section, all officers of the court, and all regulatory  
 18 agencies and officers, in using the data for investigative or prosecution purposes,  
 19 shall consider the nature of the prescriber's and dispenser's practice and the  
 20 condition for which the patient is being treated.
- 21 ~~(11)(10)~~ The data and any report obtained therefrom shall not be a public record,  
 22 except that the Department for Medicaid Services may submit the data as evidence  
 23 in an administrative hearing held in accordance with KRS Chapter 13B.
- 24 ~~(12)(11)~~ Intentional failure **to comply with the reporting requirements of this**  
 25 **section** ~~by a dispenser to transmit data to the cabinet as required by subsection (3),~~  
 26 ~~(4), or (5) of this section~~ shall be a Class B misdemeanor for the first offense and a  
 27 Class A misdemeanor for each subsequent offense.

1 ~~(13)~~<sup>(12)</sup> Intentional disclosure of transmitted data to a person not authorized by  
2 subsections<sup>[subsection]</sup> ~~(7)~~<sup>(6)</sup> to<sup>[subsection]</sup> ~~(9)~~<sup>(8)</sup> of this section or authorized  
3 by KRS 315.121, or obtaining information under this section not relating to a bona  
4 fide current or prospective patient or a bona fide specific investigation, shall be a  
5 Class B misdemeanor for the first offense and a Class A misdemeanor for each  
6 subsequent offense.

7 ~~(14)~~<sup>(13)</sup> (a) ~~The Commonwealth Office of Technology, in consultation with the~~  
8 ~~Cabinet for Health and Family Services, may submit an application to the United~~  
9 ~~States Department of Justice for a drug diversion grant to fund a pilot or continuing~~  
10 ~~project to study, create, or maintain a real-time electronic monitoring system for~~  
11 ~~Schedules II, III, IV, and V controlled substances.~~

12 (b) ~~The pilot project shall:~~

13 1. ~~Be conducted in two (2) rural counties that have an interactive real-time electronic~~  
14 ~~information system in place for monitoring patient utilization of health and social~~  
15 ~~services through a federally funded community access program; and~~

16 2. ~~Study the use of an interactive system that includes a relational data base with query~~  
17 ~~capability.~~

18 (c) ~~Funding to create or maintain a real-time electronic monitoring system for~~  
19 ~~Schedules II, III, IV, and V controlled substances may be sought for a statewide~~  
20 ~~system or for a system covering any geographic portion or portions of the state.~~

21 ~~(14) Provisions in this section that relate to data collection, disclosure, access, and~~  
22 ~~penalties shall apply to the pilot project authorized under subsection (13) of this~~  
23 ~~section.~~

24 ~~(15)~~ The Cabinet for Health and Family Services may, by promulgating an  
25 administrative regulation, limit the length of time that data remain in the electronic  
26 system. Any data removed from the system shall be archived and subject to retrieval  
27 within a reasonable time after a request from a person authorized to review data

1 under this section.

2 ~~(15)~~~~(16)~~ (a) The Cabinet for Health and Family Services shall work with each board  
3 responsible for the licensure, regulation, or discipline of practitioners,  
4 pharmacists, or other persons who are authorized to prescribe, administer, or  
5 dispense controlled substances for the development of a continuing education  
6 program about the purposes and uses of the electronic system for monitoring  
7 established in this section.

8 (b) The cabinet shall work with the Kentucky Bar Association for the  
9 development of a continuing education program for attorneys about the  
10 purposes and uses of the electronic system for monitoring established in this  
11 section.

12 (c) The cabinet shall work with the Justice and Public Safety Cabinet for the  
13 development of a continuing education program for law enforcement officers  
14 about the purposes and uses of the electronic system for monitoring  
15 established in this section.

16 ~~(16)~~~~(17)~~ If the cabinet becomes aware of a prescriber's or dispenser's failure to comply  
17 with this section, the cabinet shall notify the licensing board or agency responsible  
18 for licensing the prescriber or dispenser. The licensing board shall treat the  
19 notification as a complaint against the licensee.

20 ~~(17)~~~~(18)~~ The cabinet shall promulgate administrative regulations to implement the  
21 provisions of this section. Included in these administrative regulations shall be:

22 (a) An error resolution process allowing a patient to whom a report had been  
23 disclosed under subsection ~~(9)~~~~(8)~~ of this section to request the correction of  
24 inaccurate information contained in the system relating to that patient; and

25 (b) ~~Beginning July 1, 2013, ]~~A requirement that data be reported to the system  
26 under subsection (3) of this section within one (1) day of dispensing.

27 ➔Section 2. KRS 218A.240 is amended to read as follows:

- 1 (1) All police officers and deputy sheriffs directly employed full-time by state, county,  
2 city, urban-county, or consolidated local governments, the Department of Kentucky  
3 State Police, the Cabinet for Health and Family Services, their officers and agents,  
4 and of all city, county, and Commonwealth's attorneys, and the Attorney General,  
5 within their respective jurisdictions, shall enforce all provisions of this chapter and  
6 cooperate with all agencies charged with the enforcement of the laws of the United  
7 States, of this state, and of all other states relating to controlled substances.
- 8 (2) For the purpose of enforcing the provisions of this chapter, the designated agents of  
9 the Cabinet for Health and Family Services shall have the full power and authority  
10 of peace officers in this state, including the power of arrest and the authority to bear  
11 arms, and shall have the power and authority to administer oaths; to enter upon  
12 premises at all times for the purpose of making inspections; to seize evidence; to  
13 interrogate all persons; to require the production of prescriptions, of books, papers,  
14 documents, or other evidence; to employ special investigators; and to expend funds  
15 for the purpose of obtaining evidence and to use data obtained under KRS  
16 218A.202~~{(7)}~~ in any administrative proceeding before the cabinet.
- 17 (3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same  
18 powers of inspection and enforcement as the Cabinet for Health and Family  
19 Services.
- 20 (4) Designated agents of the Cabinet for Health and Family Services and the Kentucky  
21 Board of Pharmacy are empowered to remove from the files of a pharmacy or the  
22 custodian of records for that pharmacy any controlled substance prescription or  
23 other controlled substance record upon tendering a receipt. The receipt shall be  
24 sufficiently detailed to accurately identify the record. A receipt for the record shall  
25 be a defense to a charge of failure to maintain the record.
- 26 (5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any  
27 law enforcement authority may maintain, in its own name, an action to restrain or

1       enjoin any violation of this chapter or to forfeit any property subject to forfeiture  
2       under KRS 218A.410, irrespective of whether the owner of the property has been  
3       charged with or convicted of any offense under this chapter.

4       (a) Any civil action against any person brought pursuant to this section may be  
5       instituted in the Circuit Court in any county in which the person resides, in  
6       which any property owned by the person and subject to forfeiture is found, or  
7       in which the person has violated any provision of this chapter.

8       (b) A final judgment rendered in favor of the Commonwealth in any criminal  
9       proceeding brought under this chapter shall estop the defendant from denying  
10      the essential allegations of the criminal offense in any subsequent civil  
11      proceeding brought pursuant to this section.

12      (c) The prevailing party in any civil proceeding brought pursuant to this section  
13      shall recover his or her costs, including a reasonable attorney's fee.

14      (d) Distribution of funds under this section shall be made in the same manner as  
15      in KRS 218A.420, except that if the Commonwealth's attorney has not  
16      initiated the forfeiture action under this section, his or her percentage of the  
17      funds shall go to the agency initiating the forfeiture action.

18      (6) The Cabinet for Health and Family Services shall make or cause to be made  
19      examinations of samples secured under the provisions of this chapter to determine  
20      whether any provision has been violated.

21      (7) (a) The Cabinet for Health and Family Services shall proactively use the data  
22      compiled in the electronic system created in KRS 218A.202 for investigations,  
23      research, statistical analysis, and educational purposes and shall proactively  
24      identify trends in controlled substance usage and other potential problem  
25      areas. Only cabinet personnel who have undergone training for the electronic  
26      system and who have been approved to use the system shall be authorized  
27      access to the data and reports under this subsection. The cabinet shall notify a

1 state licensing board listed in KRS 218A.205 if a report or analysis conducted  
2 under this subsection indicates that further investigation about improper,  
3 inappropriate or illegal prescribing or dispensing may be necessary by the  
4 board. The board shall consider each report and may, after giving due  
5 consideration to areas of practice, specialties, board certifications, and  
6 appropriate standards of care, request and receive a follow-up report or  
7 analysis containing relevant information as to the prescriber or dispenser and  
8 his or her patients.

9 (b) The cabinet shall develop criteria, in collaboration with the Board of Medical  
10 Licensure, the Board of Nursing, the Office of Drug Control Policy, and the  
11 Board of Pharmacy, to be used to generate public trend reports from the data  
12 obtained by the system. Meetings at which the criteria are developed shall be  
13 meetings, as defined in KRS 61.805, that comply with the open meetings  
14 laws, KRS 61.805 to 61.850. The cabinet shall, on a quarterly basis, publish  
15 trend reports from the data obtained by the system. Except as provided in  
16 subsection (8) of this section, these trend reports shall not identify an  
17 individual prescriber, dispenser, or patient. Peace officers authorized to  
18 receive data under KRS 218A.202 may request trend reports not specifically  
19 published pursuant to this paragraph except that the report shall not identify an  
20 individual prescriber, dispenser, or patient.

21 (8) If the cabinet deems it to be necessary and appropriate, upon the request of a state  
22 licensing board listed in KRS 218A.205, the cabinet shall provide the requesting  
23 board with the identity of prescribers, dispensers, and patients used to compile a  
24 specific trend report.

25 (9) Any hospital or other health care facility may petition the cabinet to review data  
26 from the electronic system specified in KRS 218A.202 as it relates to employees of  
27 that facility to determine if inappropriate prescribing or dispensing practices are

1           occurring. The cabinet may initiate any investigation in such cases as he or she  
2           determines is appropriate, and may request the assistance from the hospitals or  
3           health care facilities in the investigation.